

K 0503/2

MAY - 9 2005

## 510(k) Summary

1.0 Date Prepared

January 14, 2005

2.0 Submitter (Contact)

Clarence Odem, III  
General Manager  
Nipro Diabetes Systems, Inc.  
Miramar, FL 32205  
(954) 435-5665

3.0 Device Name

Proprietary / Trade Name: Amigo Insulin Pump  
Common Name(s): Insulin pump

4.0 Device Classification

Classification Name: Pump, Infusion, Insulin  
Procode: 80LZG Class II 21 CFR § 880.5725

5.0 Device Description

The Amigo Insulin Pump is a small, lightweight, battery-operated programmable Insulin infusion pump. The pump houses a replaceable Nipro GlucoPro™ single-use insulin syringe containing up to 300 units of U-100 insulin. Programming is accomplished via a keypad and LCD display. A microcomputer controls the rotation of a stepper-motor which is connected to a gear reduction assembly. The output of the reduction assembly turns a lead-screw which moves a linear piston. The piston mechanically engages the plunger of the insulin syringe, and the programmed amount of insulin is dispensed through an external seal and luer lock connector to an infusion set.

6.0 Indications for Use

The Amigo Insulin Pump is intended for the subcutaneous infusion of insulin.

## 510(k) Summary (continued)

### 7.0 Substantial Equivalence

The Amigo Insulin Pump is substantially equivalent in the intended use, operating principle, overall design, performance, technology, features, functions, and materials to the GlucoPro EVA Pump as described in K013309.

Characteristic	Amigo Insulin Pump (This Submission)	GlucoPro EVA (K013309)
Intended Use	Intended for the subcutaneous infusion of insulin	Intended for the subcutaneous infusion of insulin
Pump Type	Linear Piston	Linear Piston
Control Technology	Microprocessor	Microprocessor
Insulin Reservoir	3 mL (300 Units)	3 mL (300 Units)
Insulin Type	U-100	U-100
Power Source	One 3 Volt lithium battery	One 3 Volt lithium battery
Programmable Basal Delivery	Yes	Yes
Programmable Bolus Delivery	Yes	Yes
User Notification	Audible, visual, and vibration	Audible, visual, and vibration
Visual Display	LCD	LCD
Insulin Syringe / reservoir	Nipro GlucoPro	Nipro GlucoPro
Infusion Set Connector	Standard luer lock	Standard luer lock



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY - 9 2005

Mr. Clarence Odom, III  
General Manager  
NIPRO Diabetes Systems, Incorporated  
3361 Enterprise Way  
Miramar, Florida 33025

Re: K050312

Trade/Device Name: Amigo Insulin Pump  
Regulation Number: 880.5275  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: LZG  
Dated: January 31, 2005  
Received: February 8, 2005

Dear Mr. Odom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):**

Device Name: Amigo Insulin Pump

**Indications for Use:**

The Amigo Infusion Pump is intended for the subcutaneous infusion of insulin

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
John D. D'Amato  
Division Sign-Off  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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